



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 29 2000

Ms. Linda Nelson  
Regulatory Affairs Manager  
SteriTec Products, Incorporated  
599 Topeka Way, Suite 700  
Castle Rock, Colorado 80104

Re: K002861  
Trade Name: EO Gas Sterilization Process Indicator  
Tapes, Model CI 124  
Regulatory Class: II  
Product Code: JOJ  
Dated: September 12, 2000  
Received: September 13, 2000

Dear Ms. Nelson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we ~~have~~ determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Er Timothy A. Ulatowski  
Director

Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if know): K002861

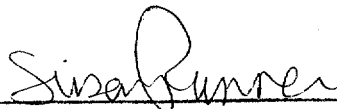
Device Name: SteriTec EO Gas Sterilization Process Indicator Tapes, Models CI 124/.5, CI 124/.75, and CI 124/1

### Indications For Use:

SteriTec EO Gas Sterilization Process Indicator Tapes are used to hold sterilization packs together and as process indicators in ethylene oxide sterilizers. The tape can be used in ethylene oxide sterilizers operating at 600 mg/l EO gas, 50% +/- 10% relative humidity, 130° F, for 45 minutes or longer. The brown words "gas" turn green after exposure to an EO gas sterilization process thus providing identification of processed items.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

File Number

K002861